

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | Kolter     | Docket No.:       | 53272                 |
| Application No.:      | 10/501,773 | Examiner:         | HAIDER, SAIRA<br>BANO |
| Filed:                | 7/20/2004  | Art Unit:         | 1796                  |
| Customer No.:         | 26474      | Confirmation No.: | 8423                  |

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| For: | Rapidly soluble film covering based on polyvinylalcohol-polyether graft copolymers combined with components containing hydroxyl, amide, or ester functions |
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Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

This is an appeal from the final rejection of claims 1, 2, 5, 7, 10, 11, 20, and 27 – 30, mailed December 10, 2007.

The fee of \$510.00 set forth in 37 C.F.R. § 41.20(b)(2) is paid by credit card. Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account 14.1437. Please credit any excess fees to such account.

REAL PARTY IN INTEREST:

The real party in interest is BASF SE, of Ludwigshafen, Germany.

RELATED APPEALS AND INTERFERENCES:

To the best of the undersigned's knowledge, there are no related interferences or judicial proceedings.

STATUS OF CLAIMS:

- Claims 1 – 30 are pending in the application.
- Claims 1, 2, 5, 7, 10, 11, 20, and 27 – 30 are rejected.
- No claims are allowed or confirmed.
- Claims 3, 4, 6, 8, 9, 12 – 19, and 21 – 26 have been withdrawn from consideration.
- No claims are canceled.

STATUS OF AMENDMENT:

No amendment to the claims or to the specification was filed subsequent to the final rejection mailed December 10, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER:

The claimed invention relates to a quick dissolving film coating composition for coating solid substrates. Examples of solid substrates that might be coated with the quick dissolving film coating composition according to the claimed invention include, but are not limited to pharmaceutical, cosmetic or agrochemical product forms, seed, dietary

supplements, and foods.<sup>1</sup> The quick dissolving film coating composition is composed of 10 – 90% by weight of a component A,<sup>2</sup> 5 – 80 % by weight component B,<sup>3</sup> and 0 – 70 % by weight of components C.<sup>4</sup> Component A is a polyvinyl alcohol-polyether graft copolymer.<sup>5</sup> Component B is at least one further component containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions.<sup>6</sup> Components C are further customary coating constituents.<sup>7</sup>

The independent claim involved in this appeal is claim 1. Claims 2, 5, 7, 10, 11, 20, and 27 – 30 depend from claim 1. Summary of the subject matter of the dependent claims is omitted as unnecessary.

#### GROUND OF REJECTION TO BE REVIEWED ON APPEAL:

Whether the Office action erred in rejecting:

- I. claims 1, 2, 5, 10, 20, 27 and 28 under 35 U.S.C. §102(b) over WO/00/18375 to Gotsche et al (hereinafter, “Gotsche”);
- II. claim 7 under 35 U.S.C. §103(a) over Gotsche in view of US 5,091,185 to Castillo (hereinafter, “Castillo”);
- III. claim 11 under 35 U.S.C. §103(a) over Gotsche et al in view of US 4,842,854 to Babaian (hereinafter, “Babaian”); and
- IV. claims 29 and 30 under 35 U.S.C. §103(a) over Gotsche.

#### ARGUMENT:

##### Regarding Rejection I:

The Office action erred by rejecting claims 1, 2, 5, 10, 20, 27 and 28 under 35 U.S.C. §102(b) over Gotsche.

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<sup>1</sup> Page 1, lines 6 – 8 of the Specification.

<sup>2</sup> Page 2, line 37 of the Specification.

<sup>3</sup> Page 2, line 40 of the Specification.

<sup>4</sup> Page 2, line 44 of the Specification.

<sup>5</sup> Page 1, lines 9 – 10 of the Specification.

<sup>6</sup> Page 1, lines 10 – 12 of the Specification.

<sup>7</sup> Page 1, lines 12 – 13 of the Specification.

Claim 1 is directed to a quick dissolving film coating composition for coating solid substrates, composed of:

**component A:** 10 – 90% by weight of a polyvinyl alcohol-polyether graft copolymer,

**component B:** 5 – 80% by weight of at least one further component containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions, and

optionally **component C.**

In order for this composition to be anticipated, “[t]he identical invention must be shown in as complete detail as is contained in the patent claim.”<sup>8</sup> Yet, the Office action states that “Component A is clearly anticipated by Gotsche [and, therefore,] the issue of species selection is irrelevant ....”<sup>9</sup>

The present invention is not merely component A. The present invention is a composition. The inventive composition must comprise component A and component B. The inventive composition must comprise 10 – 90% by weight of component A, and 5 – 80% by weight of component B. In order for the inventive composition to be anticipated a single prior art reference must show the identical composition. It is not enough that a single prior art reference discloses both components A and B in isolation.

Contrary to the statement in the Office action that the issue of species selection is irrelevant because component A is disclosed in an enormous genus, applicable law mandates that the issue of species selection is of paramount importance. Moreover, common sense and justice both demand that the issue of species selection be given due consideration. Otherwise, a sales catalogue of all known chemical compounds would anticipate any future combination of chemicals.

According to the Office action, Component A of present claim 1 is included in the enormous genus encompassed by column 3, indicated lines 5 – 41 of Gotsche (US 6,579,953), which discloses:

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<sup>8</sup> *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

<sup>9</sup> Page 5, line 21 of the final Office action mailed December 10, 2007



needed to:

- select component A from an enormous genus which is not sufficiently limited or well delineated to support anticipation,
- select component B from a second broad genus which is not sufficiently limited or well delineated to support anticipation, and
- for some unknown reason combine components A and B.

When the present invention is appropriately considered as a whole, it is clear that Gotsche does not disclose “[t]he identical invention ... in as complete detail as is contained in the patent claim.”<sup>12</sup> Thus, applicants respectfully submit that the reference does not anticipate the present invention.

Since the Office action has not rejected these claims under 35 U.S.C. §103, and since a case of *prima facie* obviousness cannot be established because of the shortcomings of Gotsche, a showing of unexpected results is in no way required. However, in order to emphasize the importance of the claimed invention, Applicants would like to make note that the present specification discloses synergistic effects which could not have been foreseen by the skilled artisan on the basis of Gotsche. As is explained on page 7, line 23 to page 9, line 35 of the specification, the combination leads to enhanced mechanical properties like elongation at break which are higher than the properties of the individual compounds or their respective proportionate values.

Moreover, as shown in the 2<sup>nd</sup> table of page 8 (reproduced below), the coatings remain stable even after 12 months.

| Parts by weight            | Elongation at break after preparation [%] | Elongation at break after storage at 23°C for 6 months [%] | Elongation at break after storage at 23°C for 12 months [%] |
|----------------------------|---|--|---|
| PVA-PEG graft copolymer 60 | 213                                       | 205  | 202   |
| Polyvinyl alcohol 40       |   |  |   |
| Polyvinyl alcohol          | 160                                       | 30   | 5   |

This stability is surprising, because the coatings contain 40% by weight of polyvinyl alcohol. Polyvinyl alcohol tends to become brittle and is not stable when stored.

<sup>12</sup> *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Regarding Rejection II:

The Office action erred by rejecting claim 7 under 35 U.S.C. §103(a) over Gotsche in view of Castillo.

Castillo is cited only in an attempt to compensate for Gotsche's failure "to disclose that component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 90 mol%."<sup>13</sup> Thus, even before analyzing whether an apparent reason existed for a skilled artisan to combine these two references, one can conclude that claim 7 is unobvious over the cited combination. As discussed above, Gotsche is inadequate to establish a case of *prima facie* obviousness with regard to the invention of claim 1. The reference provides no apparent reason to select component A from an enormous genus, no apparent reason to select component B from a broad genus, and no apparent reason to combine component A and component B. In other words, claim 1 could not properly be rejected under 35 U.S.C. §103(a) over Gotsche in view of Castillo. It is well-settled that "if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."<sup>14</sup> Thus, claim 7, which depends from claim 1, is nonobvious.

For the sake of completeness, Applicants reemphasize that the film coatings according to the present invention are meant to dissolve quickly. A skilled artisan, aiming at a quick dissolving film coating would not have added the component utilized by Castillo to the film coating of Gotsche, because the Castillo component is utilized to reduce the rate of release of a film coating on a pharmaceutical presentation. In response, the Office action states that Col. 5, lines 29 – 38 of Castillo "teaches that polymers less than 100% hydrolyzed will result in a[n] increase in the rate of release."<sup>15</sup> This statement is inaccurate. The cited portion of the reference states:

The water sensitivity of PVA, or the rate at which it goes into solution, is controlled primarily by the degree of hydrolysis. Fully hydrolyzed polymers have a high degree of water resistance, and dissolve very slowly at temperatures below about 60°C. For purposes of the

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<sup>13</sup> Page 3, lines 16 – 17 of the Office action of December 10, 2007.

<sup>14</sup> MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

<sup>15</sup> Page 7, lines 9 – 10 of the final Office action mailed December 10, 2007

present invention, a low level of water sensitivity is desired and fully hydrolyzed polymers are preferred. Water sensitivity of PVA is also influenced to a lesser degree by molecular weight, with higher molecular weight polymers having increased water resistance.<sup>16</sup>

Finally, the Office action seems to have overlooked the synergistic effects disclosed in the present specification, which could not have been foreseen by the skilled artisan on the basis of Gotsche. As is explained on page 7, line 23 to page 9, line 35 of the specification, the combination leads to enhanced mechanical properties like elongation at break which are higher than the properties of the individual compounds or their respective proportionate values. Since the coatings contain 40% by weight of polyvinyl alcohol, a polymer which tends to become brittle and is not at all stable when stored on its own, the results shown on the 2<sup>nd</sup> table of page 8, reporting elongation at break after various storage times are especially surprising. The coatings remain stable even after 12 months.

#### Regarding Rejection III:

The Office action erred by rejecting claim 11 under 35 U.S.C. §103(a) over Gotsche in view of Babaian. Claim 11 depends from claim 1. The Office action does not cite Babaian to compensate for the fact that a skilled artisan had no apparent reason to make the proposed selections and combinations from Gotsche. Instead, the Office action cites Babaian in an attempt to compensate for the fact that “Gotsche fails to disclose that component B comprises vinylpyrrolidone-(meth)acrylate copolymers.”<sup>17</sup> Thus, claim 1 could not properly be rejected under 35 U.S.C. §103(a) over Gotsche in view of Babaian. It is well-settled that “if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.”<sup>18</sup> Thus, claim 11 is unobvious, and the present rejection should be overturned.

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<sup>16</sup> Col. 5, lines 29 – 38 of US 5,091,185.

<sup>17</sup> Page 4, lines 17 – 18 of the present Office action.

<sup>18</sup> MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).



Regarding Rejection IV:

The Office action erred by rejecting claims 29 and 30 under 35 U.S.C. §103(a) over Gotsche. Claims 29 and 30 require components A and B and also require a minimum of 5% by weight of component C. More importantly, both of these claims depend from claim 1, and it is well-settled that “if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.”<sup>19</sup> As discussed above, claim 1 is unobvious over Gotsche. Thus, claims 29 and 30 are unobvious, and the rejection should be overturned.

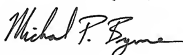
In Conclusion:

Applicants respectfully submit that the present application is in condition for allowance, and request favorable action in this matter.

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<sup>19</sup> MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

CLAIMS APPENDIX:

1. (original) A quick dissolving film coating composition for coating solid substrates, composed of
  - a) 10 - 90% by weight of a polyvinyl alcohol-polyether graft copolymer (component A),
  - b) 5 - 80% by weight of at least one further component containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions (component B), and
  - c) 0 - 70% by weight of further customary coating constituents (components C).
2. (original) A composition as claimed in claim 1, wherein component B is a polymer.
3. (withdrawn - original) A composition as claimed in claim 1, wherein component B is a sugar, a sugar alcohol, or a derivative thereof.
4. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B is a highly disperse silica having a specific surface area w 100 m<sup>2</sup>/g.
5. (previously presented) A composition as claimed in claim 1, wherein component B is a polymer selected from the group consisting of polyvinyl alcohols, polysaccharides, celluloses, starches, gelatin, polyvinylpyrrolidones, vinylpyrrolidone-vinyl acetate copolymers, vinylpyrrolidone-methacrylate copolymers,

vinylpyrrolidone-acrylate copolymers, (meth)acrylate copolymers, hydroxyalkyl (meth)acrylate copolymers, polyvinyl acetates, polylactides, polyethylene glycols, polypropylene glycols, polyethylene glycol-polypropylene glycol block copolymers, and derivatives thereof.

6. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B is a compound selected from the group consisting of lactose, sucrose, glucose, xylose, mannitol, sorbitol, xylitol and isomalt.
7. (previously presented) A composition as claimed in claim 1, wherein component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 99 mol%.
8. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxyethylmethylcellulose, methylcellulose, ethylcellulose, carboxymethylcellulose, cellulose, and microcrystalline cellulose.
9. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B is selected from the group consisting of alginates, including propylene glycol alginates, carrageenans, pectins, guar, tara, xanthans, gum arabic, chitosans, and salts

thereof.

10. (previously presented) A composition as claimed in claim 1, wherein component B is selected from the group consisting of N-vinylpyrrolidone homopolymers, crosslinked polyvinylpyrrolidones, polyvinyl acetate, and N-vinylpyrrolidone-vinyl acetate copolymers.
11. (previously presented) A composition as claimed in claim 1, wherein component B comprises vinylpyrrolidone-acrylate copolymers or vinylpyrrolidone-methacrylate copolymers.
12. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises (meth)acrylate copolymers or hydroxyalkyl (meth)acrylate copolymers.
13. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises a 1:2:1 butyl methacrylate-2-dimethylaminoethyl methacrylate-methyl methacrylate copolymer, a methacrylic acid-methyl methacrylate copolymer, a 1:1 methacrylic acid-ethyl acrylate copolymer or a salt thereof.
14. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises starch, starch derivatives, starch hydrolyzates, amylose, cyclodextrins, maltodextrins, glucose syrups, dextrins, inulin, polydextrose or polyfructose.

15. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises lactose, glucose, xylose or sucrose.
16. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises isomalt.
17. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises mannitol, sorbitol or xylitol.
18. (withdrawn - original) A composition as claimed in claim 1, wherein component B comprises urea.
19. (withdrawn - previously presented) A composition as claimed in claim 1, wherein component B comprises a highly disperse silica having a specific surface area w 100 m<sup>2</sup>/g.
20. (previously presented) A composition as claimed in claim 1, wherein components C comprise dyes, lakes, pigments, detackifiers, fillers, shine enhancers, wetting agents, surfactants, foam preventatives, protective colloids, buffer substances, pH regulators, and plasticizers.
21. (withdrawn - previously presented) A process for producing coated substrates, which comprises stirring a film coating composition as claimed in claim 1 into water and applying it to the substrate by means of an appropriate spraying means, the film coating being

dried gradually by supplying heated air.

22. (withdrawn - original) A process as claimed in claim 21, wherein before adding it to water said composition is either dry mixed or compacted or granulated and is introduced as a premix into water.
23. (withdrawn - original) A process as claimed in claim 21, wherein components A and B and also components C minus the coloring components are dry mixed or compacted or granulated and that preparation is stirred into water before or together with the coloring components.
24. (withdrawn - previously presented) A process as claimed in claim 21, wherein a mixture of components A and B is subjected from aqueous solution to spray drying, fluidized bed drying or roller drying and this powder, with components C, is stirred into water.
25. (withdrawn - previously presented) A process as claimed in claim 21, wherein a mixture of components A and B is subjected from aqueous solution to spray drying, fluidized bed drying or roller drying and this powder is granulated or compacted or mixed with components C and is stirred into water as such a mixture.
26. (withdrawn - previously presented) A process as claimed in claim 21, wherein components A and B and also components C minus the coloring components are subjected from aqueous solution to spray drying,

- fluidized bed drying or roller drying and the resultant powder, where appropriate with the coloring component, is stirred into water.
27. (previously presented) A solid substrate coated with a film coating of claim 1.
28. (original) A substrate as claimed in claim 26, selected from pharmaceutical, cosmetic, and agrochemical product forms, seed, dietary supplements, and foods.
29. (previously presented) The coating composition claimed in claim 1, composed of
- a) 10 - 90% by weight component A,
  - b) 5 - 80% by weight of component B, and
  - c) 5 - 70% by weight of components C.
30. (previously presented) The coating composition claimed in claim 1, composed of
- a) 20 - 80% by weight component A,
  - b) 10 - 70% by weight of component B, and
  - c) 5 - 60% by weight of components C.

EVIDENCE APPENDIX:

None.

RELATED PROCEEDINGS A APPENDIX:

None.